indicated in Appendix A. The amendments follow the revised format of the January 31, 2003 Pre-OG notice.

REMARKS

Claim 1 has been amended. Steps a) and b) have been combined into a single step and reworded for clarification. Precipitants are involved in two distinct steps of the method claimed. It has also been clarified that the precipitant used during foaming of the composition, and the precipitant that is subsequently used in the bath to stabilise the cured foam, may be different. This is supported by Example 4 on pages 23 to 24 of the specification as filed. Also, the restriction relating to the nature of the first precipitant has been removed from the wording of Claim 1 and introduced in a newly submitted dependent Claim 28.

Claim 2 is reworded for clarification and in order to refer to newly worded step a) of Claim 1.

In Claim 3 the term "carboxymethylcellulose" has been removed to overcome the Examiner's rejection.

Two typographical mistakes in Claims 3 and 4 respectively are corrected.

In Claim 7 the term "formulation" has been replaced by "sterile foam" to be consistent with the amended wording of Claim 1.

Claim 24 is amended in order to identify the precipitant mentioned in this claim as being the second precipitant and to be consistent with the wording of amended Claim 1.

New Claim 27 has been introduced. The subject matter of this Claim is directed to the subject matter of former Claim 6, now deleted.

None of the prior art documents cited by the Examiner discloses a method of providing a sterile foam as now specified in Claim 1. Furthermore, none of the prior art documents cited disclose a step of bathing the cured foam in a precipitant prior to sterilisation.

Bakis et al discloses the use of a bath of Ca^{2+} ions to stabilise the foam by cross-linking. However, it does not disclose the use of a foam wherein a first precipitant has been used during foaming. Moreover it does not relate to the problem of sterilisation of the foam. There is indeed no indication or suggestion in Bakis et al. that the foam would be suitable for sterilisation.

Gilchrist et al (WO 96/17595) describes a foam comprising a gelling agent and a calcium ion releasing water soluble glass. It is reiterated that Gilchrist et al. does not teach immersing the foamed formulation in a precipitant bath, sterilising the foam (as opposed to a gel formulation) though exposure to gamma-irradiation or ethylene oxide. The Examiner is respectfully requested to point out the specific passages of Gilchrist et al. which would disclose the above characteristics; in particular the immersion of the cured foam in a precipitant bath, as required in the present claims.

It is further contested that the disclosure of Gilchrist et al. describes a sterilised foam. Gilchrist et al. only states that the foam could be sterilised. However it was later found that the sterilisation had a deleterious effect on the foam and therefore the suggestion of Gilchrist et al. that the foam described therein could be readily sterilised was erroneous. This is evidenced by the Declaration made by one of the co-inventors of Gilchrist et al., (see in particular paragraphs 5 and 6 of the Declaration). Thus the method of manufacturing foams described in Gilchrist et al. leads to foam that cannot be satisfactorily sterilised by gamma-irradiation of ethylene oxide.

Therefore it is believed that the presently submitted set of Claims are now allowable and that the Examiner's previous rejection under 35 U.S.C 102, 103 and 112 have been overcome by the amendment of the Claims.

Allowance of the application is therefore solicited.

Respectfully submitted,

THOMAS GILCHRIST, ET AL.

By:_____

DANIEL A. MONACO
Registration No. 30,480
Drinker Biddle & Reath, LLP
One Logan Square
18th and Cherry Streets
Philadelphia, PA 19103-6996
(215) 988-3312
(215) 988-2757 - Fax
Attorney for the Applicants

APPENDIX A - AMENDMENTS TO THE CLAIMS

1. (Currently amended) A process of producing a sterile foam for medical or veterinary use, said process comprising the following steps:

C1

a) ~~foaming~~ forming a physiologically acceptable ~~formulation~~ foam for application to a body ~~as a foam~~, said ~~formulation~~ foam comprising a foamble gelling agent~~; b) treating said foamed formulation~~, and wherein said foam is treated with a first precipitant ~~which is calcium citrate or a calcium ion releasing water soluble glass~~, and wherein said first precipitant is combined with said gelling agent before or during the foaming of the gelling agent and stabilises the gelling agent;

~~c)~~b) allowing the foam thus obtained to cure;

~~d)~~c) immersing the cured foam in a bath of ~~said~~ a second precipitant to form a treated foam;

~~e)~~d) drying the treated foam; and

~~f)~~e) sterilising said dried treated foam by exposure to gamma-irradiation or ethylene oxide.

2. (Currently amended) A process as claimed in Claim 1, wherein said precipitant is packaged separately to said foamable gelling agent prior to ~~foaming~~ forming the physiologically acceptable foam of step a).

3. (Currently amended) A process as claimed in Claim 1, wherein said gelling agent is alginate, ~~carboxymethylcellulose~~, collagen, a polysaccharide, agar, a polyethylene oxide, a glycol ~~metacrylate~~ methacrylate, carageenan gel, gelatin, a gum, or salt of any of these, or mixtures thereof.

4. (Currently amended) A process as claimed in Claim 3 wherein said gelling agent is alginate, carboxymethyl-cellulose, salts thereof, or mixtures thereof.

5. (Previously amended) A process as claimed in Claim 1, wherein said gelling agent has a molecular weight of from 10,000 to 200,000 kDa.

6. Cancelled.

C1 Cont

7. (Currently amended) A process as claimed in Claim 1, wherein said ~~formulation~~ sterile foam further contains a foaming agent.

8. (Previously amended) A process as claimed in Claim 7, wherein said foaming agent is cetrimide, lecithin, a soap, silicone, or a surfactant.

9-10. (Cancelled).

11. (Previously amended) The process of Claim 1, wherein said formulation further comprises an organic acid in an amount of 0.5 g to 5.0 g per 100 g of gelling agent.

12-21. (Cancelled).

22. (Previously amended) The process of Claim 1, wherein said foam is washed in a de-ionised water/glycerine mixture prior to drying.

23. (Previously amended) The process of Claim 1 wherein the foam is oven dried at temperatures below 100°C.

24. (Currently amended) The process of Claim 1 wherein ~~the foam~~ said second precipitant is a ~~immersed in a bath of~~ calcium citrate solution ~~as precipitant~~.

25. (Previously added) The process of Claim 1, wherein said treated foam is washed.

26. (Previously added) A foam obtained in accordance with the process of Claim 1.

Cl. contd

27. (New) The process of Claim 1, wherein said first or second precipitant is independently a salt of calcium, zinc, copper, silver or aluminium; borates; glyoxal; or amino-formaldehyde pre-condensates.

28. (New) The process of Claim 1, wherein said first precipitant is calcium citrate or a calcium releasing water soluble glass.